



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2022-0070]

**Availability of Final Guidelines for Examining Unusual
Patterns of Cancer and Environmental Concerns**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: General Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR), located within the Department of Health and Human Services (HHS) announces the availability of the final *Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns* (2022 Guidelines). The 2022 Guidelines provide updates to the 2013 publication, *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from the CDC and the Council of State and Territorial Epidemiologists (CSTE)*. The updates provide state, tribal, local, and territorial health departments guidance for a revised and expanded approach to evaluating concerns about unusual patterns of cancer in communities, including those associated with local environmental concerns. The 2022 Guidelines finalize the draft guidelines issued on May 25, 2022.

DATES: The 2022 Guidelines are available [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Amy Lavery, Centers for Disease Control and Prevention, National Center for Environmental Health, Division of Environmental Health Science and Practice, 4770 Buford Highway NE, Mailstop F-60, Atlanta, GA 30341; Telephone: 770-488-4024; Email: CCGuidelines@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background

CDC/ATSDR is announcing the availability of final *Guidelines for Examining Unusual Patterns of Cancer and Environmental Concerns* (2022 Guidelines). The 2022 Guidelines are an update to the 2013 guidelines, *Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists* (2013 Guidelines). CDC/ATSDR develops guidance for state, tribal, local, and territorial (STLT) health departments on how to respond to cancer cluster concerns. The 2022 Guidelines are a tool to assist STLT public health agencies in applying a systematic approach when responding to inquiries about suspected unusual patterns of cancer in residential or community settings.

In the 2022 Guidelines, CDC/ATSDR has updated and expanded the 2013 Guidelines to provide STLT public health

agencies and other interested parties with access to information about current scientific tools and approaches to assess and respond to potential unusual patterns of cancer in communities.

CDC/ATSDR developed the 2022 Guidelines using input from a variety of sources, including STLT public health agencies, subject matter experts from academia and non-governmental organizations, an internal CDC/ATSDR steering committee, public comments received from an announcement in the Federal Register (84 FR 21786), and focus groups conducted with community members and organizations that have been involved with cancer concerns in their communities. CDC/ATSDR also gathered input from a comprehensive literature review and media scan and evaluated advances in the field of environmental epidemiology (e.g., geospatial methods) and community engagement strategies.

On May 25, 2022 CDC/ATSDR published a notice in the *Federal Register* announcing the availability of the draft 2022 Guidelines (87 FR 31888). The notice gave the public an opportunity to submit comments by July 25, 2022.

CDC/ATSDR received 46 sets of comments from state health departments, community members, academicians, clinicians, cancer registries, non-governmental organizations, and private consultants on behalf of trade associations (<https://www.regulations.gov/docket/CDC-2022->

0070/comments). A summary of the comments received and the modifications CDC/ATSDR made to the draft 2022 Guidelines after careful consideration are below:

- Commenters stated the terms “cancer cluster” and “unusual patterns of cancer” were used interchangeably throughout the document without clear definition of both terms.
 - Response: CDC/ATSDR provided a clear definition of both terms.
- Commenters noted that it was unclear whether every proactive evaluation must result in the criteria assessment. Commenters questioned how the criteria assessment differs from the response from an incoming inquiry.
 - Response: CDC/ATSDR added language to clarify the response to both proactive monitoring and incoming inquiries and provided examples on how to respond to unusual patterns of cancer identified in the proactive monitoring. CDC/ATSDR refined the flow chart in Figure 1, which provides a summary of the enhanced process for evaluating patterns of cancer routinely and evaluating community inquiries about unusual patterns of cancer and environmental concerns. CDC/ATSDR also clarified the discussion on proactive evaluation and routine monitoring of cancer data, including clarifying the need for collaboration with other health agency programs to

determine the need for further evaluation through the criteria assessment

- Commenters noted that the discussion of challenges and limitations was important to mention early in the guidelines document, rather than in later sections of the document.

- Response: CDC/ATSDR added information on limitations and challenges related to implementation of the recommendations provided within the guidelines early in the document and then reinforced these limitations later in the document.

- Several comments were focused on clarifying phases and the intent of various criteria, as well as the need for examples to enhance clarity.

- Response: CDC/ATSDR made editorial changes to improve clarity and provided examples when possible, such as including examples of specific partners within a public health agency to engage on unusual patterns of cancer.

CDC/ATSDR endeavored to improve clarity with respect to certain components of the criteria. For example, CDC/ATSDR changed step 8 of the criteria from "Is there known biologic plausibility of the cancer(s) of concern with suspected environmental contaminants in terms of disease etiology?" to "Is there a

plausible pathway of exposure between the suspected environmental contaminants and the cancer(s) of concern in terms of disease etiology?" This change allowed for a clearer depiction of the intent of step 8 of the criteria.

- Some commenters raised the issue of how frequent and regular routine monitoring of cancer may place additional burdens on public health agency resources.
 - Response: 50% of states reported through the STLT survey that they already conduct routine monitoring of cancer incidence data. However, CDC/ATSDR acknowledged, within the 2022 Guidelines, that resource limitations may impact the frequency with which routine monitoring can be carried out. CDC's National Environmental Public Health Tracking Program (<https://www.cdc.gov/nceh/tracking/default.htm>) worked with state cancer registries and tracking partners to make three- and five-year rates more readily available, to reduce the burden on states with respect to monitoring.
- Commenters suggested that providing more references would be helpful.
 - Response: CDC/ATSDR added additional references throughout the 2022 Guidelines.

- Commenters noted that more guidance and instructions are needed on the use of the Cancer Inquiry intake form.
 - o Response: CDC/ATSDR is developing an instructions document for STLT public health agencies to use as a supplement to the Cancer Inquiry intake form.
- Commenters noted that more details and resources were needed on use of the standardized incidence ration, such as specific minimum thresholds.
 - o Response: CDC/ATSDR is developing additional education and resource tools and will post on the National Center for Environmental Health's Health Studies website once available.

For more information about the process of updating the 2022 Guidelines, please visit <https://www.cdc.gov/nceh/cancer-environment/index.html>.

Availability of the Final 2022 Guideline: The Final 2022 Guidelines can be found in the Supporting & Related Materials tab of this docket found on the Federal eRulemaking Portal: <https://www.regulations.gov>, identified by Docket No. CDC-2022-0070.

Angela K. Oliver,
Executive Secretary,

Centers for Disease Control and Prevention.

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